# **Complete Summary**

#### **GUIDELINE TITLE**

Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin.

# **BIBLIOGRAPHIC SOURCE(S)**

National Institute for Health and Clinical Excellence (NICE). Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Oct. 33 p. (Technology appraisal guidance; no. 159).

## **GUIDELINE STATUS**

This is the current release of the guideline.

# **COMPLETE SUMMARY CONTENT**

SCOPE

**DISCLAIMER** 

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS CONTRAINDICATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES IDENTIFYING INFORMATION AND AVAILABILITY

# **SCOPE**

# **DISEASE/CONDITION(S)**

Chronic pain of neuropathic or ischemic origin

#### **GUIDELINE CATEGORY**

Assessment of Therapeutic Effectiveness Management Treatment

#### **CLINICAL SPECIALTY**

Anesthesiology
Cardiology
Family Practice
Internal Medicine
Neurological Surgery
Neurology
Surgery

## **INTENDED USERS**

Advanced Practice Nurses Nurses Physician Assistants Physicians

# **GUIDELINE OBJECTIVE(S)**

To evaluate the clinical and cost effectiveness of spinal cord stimulation (SCS) for chronic pain of neuropathic or ischemic origin

## **TARGET POPULATION**

Adults with chronic neuropathic or ischemic pain

#### INTERVENTIONS AND PRACTICES CONSIDERED

Spinal cord stimulation (SCS) as a treatment option for chronic pain of neuropathic origin

**Note**: Spinal cord stimulation for treatment of chronic pain of ischemic origin was considered but not recommended.

#### **MAJOR OUTCOMES CONSIDERED**

- Clinical effectiveness
  - Pain
  - Health-related quality of life
  - Physical and functional abilities
  - Anxiety and depression
  - Medication use
  - Complications and adverse effects (e.g., procedural complications and technical failures)
- Cost-effectiveness

# **METHODOLOGY**

# METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

# **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this appraisal was prepared by the School of Health and Related Research (ScHARR), University of Sheffield (see the "Availability of Companion Documents" field).

# **Clinical Effectiveness**

#### **Identification of Studies**

A comprehensive search was undertaken to systematically identify clinical effectiveness literature concerning spinal cord stimulation in adults with chronic neuropathic or ischaemic pain.

The search strategy comprised the following main elements:

- Searching of electronic databases
- Contact with experts in the field
- Scrutiny of bibliographies of retrieved papers

The following databases were searched from inception: Medline, Embase, CINAHL, BIOSIS, the Cochrane Database of Systematic Reviews (CDSR), the Cochrane Controlled Trials Register (CCTR), the Science Citation Index and the National Health Service (NHS) Centre for Reviews and Dissemination databases (Database of Abstracts of Reviews of Effectiveness [DARE], NHS Economic Evaluation Database [NHS EED], Health Technology Assessment [HTA]) and Office of Health Economics-[OHE] Health Economic Evaluation Database [HEED]. Pre-Medline was also searched to identify any studies not yet indexed on Medline. Current research was identified through searching the National Research Register (NRR), the Current Controlled Trials register and the Medical Research Council (MRC) Clinical Trials Register. Sources such as Google Scholar were searched. The tables of contents from key journals were searched online: Neuromodulation, Journal of Neurosurgery, British Journal of Neurosurgery, Pain, European Journal of Pain. In addition, websites for specific conditions causing chronic neuropathic/ischaemic pain were browsed, e.g., International Research Foundation for Complex Regional Pain Syndrome, International Neuromodulation Society, Neuromodulation Society of UK and Ireland, British Pain Society, European Federation of Chapters of the International Association for the Study of Pain (IASP), the European Taskforce quidelines for neurostimulation therapy for neuropathic pain on the European Federation for Neurological Societies (EFNS) website. Any industry submissions, as well as relevant systematic reviews were hand-searched in order to identify any further clinical trials. Searches were not restricted by language, date or publication type.

The MEDLINE search strategy is presented in Appendix 2 of the Assessment Report (see the "Availability of Companion Documents" field).

Literature searches were conducted from August 2007 to September 2007. References were collected in a database, and duplicates removed.

#### **Inclusion and Exclusion Criteria**

Inclusion Criteria

#### Intervention

Spinal cord stimulator devices

This included spinal cord stimulators with implantable pulse generator systems (non-rechargeable and rechargeable) and spinal cord stimulators with radio-frequency receiver systems.

## Population

 Adults with chronic neuropathic or ischaemic pain who have had an inadequate response to medical or surgical treatment (appropriate to condition) other than spinal cord stimulation (SCS)

#### Comparator

Medical and/or surgical treatment (appropriate to condition) that does not include SCS

# **Outcomes**

- Pain
- Health-related quality of life
- Physical and functional abilities
- Anxiety and depression
- Medication use
- Complications and adverse effects (e.g., procedural complications and technical failures)

# Study Types

Published papers were assessed according to the accepted hierarchy of evidence, whereby meta-analyses of randomised controlled trials (RCTs) are taken to be the most authoritative forms of evidence, with uncontrolled observational studies the least authoritative. Data from non-randomised studies were not included as evidence for relevant populations and outcomes available from RCTs. Systematic reviews were checked for RCTs that met the inclusion criteria of this review. Systematic reviews, not restricted to reviews of only RCTs, were retained for discussion some of which included controlled trials and also covered case series. Case series are considered methodologically weak because they lack a control group, so the prognosis in untreated or differently treated patients is unknown and any effect shown cannot be definitely attributed to the treatment alone, and they are prone to selection bias, and as with other non-randomised studies would expect bias toward positive results.

#### Exclusion Criteria

Trials were excluded if the intervention was neurostimulation that involves stimulation of other parts of the nervous system (e.g., peripheral nerves, deep brain), patients with prior use of SCS, pregnancy, children, or if the trial was only published in languages other than English.

Based on the above inclusion/exclusion criteria, study selection was made by one reviewer.

# **Cost-Effectiveness**

# **Systematic Review of Existing Economic Literature**

# Search Strategy

Studies were identified through searches of MEDLINE (1996-present), EMBASE (from 1996), Cochrane Database of Systematic Reviews (CDSR), and the NHS Centre for Reviews and Dissemination databases (DARE, NHS EED, HTA). All searches were undertaken between August and September 2007. A list of the keyword strategies and the sources consulted are given in Appendix 2 of the Assessment Report (see the "Availability of Companion Documents" field).

# Inclusion and Exclusion Strategy

The titles and abstracts of papers identified through the searches outlined above were assessed for inclusion using the following criteria:

# Inclusion Criteria

- Cost-effectiveness analyses as opposed to cost-benefit or cost minimisation
- UK setting
- SCS as one of the studied alternatives (possibly combined with other interventions such as usual treatment)
- The benefits were estimated in terms of cost per life-years saved (LYS) or cost per quality adjusted life years (QALYs)
- Adult populations
- The study was published in English

## Exclusion Criteria

- Studies that adapted published evaluations for other settings
- Studies that do not report results in terms of ICERs

Reviews discussing cost-effectiveness studies of SCS treatment were not included in this review but were retained for use in discussion. Non-UK cost-effectiveness studies were retained and used to inform on possible modelling methodologies.

# NUMBER OF SOURCE DOCUMENTS

# **Clinical Effectiveness**

Citations accepted into review: n=38

- 27 citations of 11 trials
- 11 citations of 9 systematic reviews

#### **Cost-Effectiveness**

- Studies included in this review: n = 1
- The manufacturers of spinal cord stimulation (SCS) devices submitted a joint cost-effectiveness model

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

**Expert Consensus** 

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

## METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this appraisal was prepared by the School of Health and Related Research (ScHARR), University of Sheffield (see the "Availability of Companion Documents" field).

## **Clinical Effectiveness**

# **Data Abstraction, Critical Appraisal Strategy and Synthesis**

Data were extracted with no blinding to authors or journal. Quality was assessed according to criteria based on National Health Service Centre for Reviews and Dissemination (NHS CRD) Report No.4. The quality assessment form is shown in Appendix 3 of the Assessment Report (see the "Availability of Companion Documents" field). The purpose of such quality assessment was to provide a narrative account of trial quality for the reader. Data were extracted by one reviewer using a standardised form (see Appendix 6 of the Assessment report [see the "Availability of Companion Documents" field]). Pre-specified outcomes were tabulated and discussed within a descriptive synthesis.

# **Cost-Effectiveness**

# **Systematic Review of Existing Economic Literature**

Quality Assessment Strategy

The quality of studies was assessed using a combination of key components of the British Medical Journal checklist for economic evaluations together with the Eddy checklist on mathematical models employed in technology assessments.

# **Review of the Manufacturers' Economic Evaluation**

Overview of the Model Submitted by the Association of British Healthcare Industries (ABHI)

The model is defined as a two-stage model that uses a decision-analytical model for the short-term treatment (first six-months) and a Markov process post six months and up to 15 years. Six mutually exclusive health states are defined: optimal pain relief with no complications, optimal pain relief with complications, sub-optimal pain relief with no complications, sub-optimal pain relief with complications, no perceived pain relief and death due to all cause of mortality (more details in Appendix 8 of the Assessment Report [see the "Availability of Companion Documents" field]).

Probabilities of events are based on three 6-month randomised controlled trials (RCTs) that examined spinal cord stimulation (SCS) in the treatment of FBSS (n=60, n=100) and CRPS (n=54). The treatment success is defined as having a pain reduction of at least 50%. It is assumed that after the first six months the patients will remain in their present health states and will enter the Markov process. A three-month cycle is used and a probability of having complications is introduced. It is assumed that the complication is resolved within a cycle. Costs and benefits are discounted at 3.5%, as per current NICE guidelines.

# **Independent Economic Assessment by ScHARR**

Neuropathic Pain

A two-stage model was developed to explore the cost and health outcomes associated with a 15-year time period of treatment using a UK NHS perspective. A decision tree was used to model the first six months of treatment. The decision tree model was extended by a Markov model used to determine the cost and health outcomes over a 15-year time horizon. This time horizon was taken from the observational study conducted by Kumar et al., that presents a Kaplan-Meier survival curve that illustrates subsequent gradual loss of pain control during a 15 year period. Published RCT data are used to determine the treatments' efficacy and the results are presented in terms of incremental cost effectiveness ratios (ICERs).

Refer to Sections 6.2 and 6.3 of the Assessment Report (see the "Availability of Companion Documents" field) for more information on methods used to analyze cost-effectiveness.

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

#### Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

# **Technology Appraisal Process**

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

# Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who

are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

## **COST ANALYSIS**

A single joint submission was received from Boston Scientific, Neuromodulation Systems, and Medtronic. This submission, which included an economic evaluation, was coordinated by the Association of British Healthcare Industries (ABHI). The Assessment Group also developed their own economic evaluation. Both the manufacturers' and Assessment Group's models used a similar structure.

#### The Manufacturers' Submission

The submission received from the manufacturers evaluated the cost effectiveness of spinal cord stimulation (SCS) for the treatment of neuropathic pain and modelled both failed back surgery syndrome (FBSS) (SCS with conventional medical management [CMM] compared with either CMM alone or repeat operation in combination CMM) and complex regional pain syndrome (CRPS) (SCS with CMM compared with CMM alone). Ischaemic pain conditions were not modelled. The model included two-stages: a decision tree for short-term treatment with SCS (first 6 months), followed by a Markov process for SCS treatment from 6 months to 15 years. Probabilities of events were based on data from the randomised controlled trials (RCTs) of FBSS and CRPS. The time frame in the second stage of the model was based on an observational study that investigated clinical predictors of outcomes for people using SCS systems over a 15-year period. Treatment success was defined as 50% or greater reduction in pain.

For FBSS, the model produced an incremental cost-effectiveness ratio (ICER) of 9,155 pounds sterling per quality-adjusted life year (QALY) gained when SCS in combination with CMM was compared with CMM alone. A comparison of SCS and CMM with repeat operation and CMM produced an ICER of 7,954 pounds sterling per QALY gained. For CRPS, the model produced an ICER of 18,881 pounds sterling per QALY gained for SCS and CMM compared with CMM. Sensitivity analyses demonstrated that the model was sensitive to assumptions about device longevity and device cost.

## **Assessment Group's Economic Evaluation of Neuropathic Pain**

The Assessment Group developed a two-stage model, comprising a decision tree to 6 months with a Markov process extending to 15 years. Both FBSS and CRPS conditions were modelled using data from the two trials of FBSS and the trial of CRPS. For FBSS, SCS in combination with CMM was compared in the model with CMM alone, and with repeat operation in combination with CMM (the latter is referred to in the remainder of the document as 'repeat operation'). For CRPS, SCS in combination with CMM was compared with CMM alone. Patients entered

into the second stage of the model in the same health state that they were assigned to at the end of the first 6 months (in the first stage of the model). The time frame was based on an observational study that investigated clinical predictors of outcomes for people using SCS systems over a 15-year period.

For FBSS, the ICERs for SCS in combination with CMM, when assuming device longevity of 4 years and using a device price figure of 9,000 pounds sterling, were 10,480 pounds sterling per QALY gained compared with CMM alone and 9,219 pounds sterling per QALY gained compared with repeat operation.

For CRPS, SCS in combination with CMM compared with CMM alone, when assuming device longevity of 4 years and using a device price of 9000 pounds sterling, produced an ICER of 32,282 pounds sterling per QALY gained.

The Assessment Group model – using utilities from the CRPS trial, a device cost of 9,000 pounds sterling and device longevity of 4 years – produced an ICER of 16,596 pounds sterling per QALY gained for SCS compared with CMM.

# **Assessment Group's Economic Evaluation of Ischaemic Pain**

The Assessment Group did not carry out an economic analysis of critical limb ischaemia (CLI), but explored the cost effectiveness of SCS for the treatment of refractory angina (RA) using an alternative modelling approach. A threshold analysis was presented based on a mathematical model that incorporated data from a prospective observational study.

## **Consideration of Evidence**

The Committee examined the economic modelling that had been carried out for the appraisal. It noted that both the model by the Assessment Group and that submitted by the manufacturers had a similar structure.

The Committee noted that there were a range of SCS systems available at different prices. The Committee heard from clinical specialists that one of the factors affecting the choice of device was the complexity of pain pattern and the extent of pain. For example, a person with a single painful limb may be expected to derive greater longevity from the same device than someone with a more complex pain pattern or greater body area affected. Clinical specialists suggested that device longevity may regularly exceed 4 years, even with a non-rechargeable device. The Committee therefore recognised that price and longevity may be interdependent and that longevity varies depending on an individual's pain characteristics.

The Committee considered the estimates of cost effectiveness for SCS in the treatment of FBSS. The Committee noted that the manufacturers' and Assessment Group's models produced similar estimates of the ICERs for the use of SCS compared with alternative treatments, and that these were less than 11,000 pounds sterling per QALY gained for the base-case analyses. The Committee was persuaded that the use of SCS for the treatment of FBSS would be a cost-effective use of NHS resources.

The Committee examined the estimates of cost effectiveness for SCS in the treatment of CRPS. It noted that the Assessment Group's and the manufacturers' models had used different sources of utility data and that neither captured the utility of a person with CRPS accurately, as one source was a trial of FBSS and the other a wider survey of neuropathic pain conditions. The Committee noted the additional utility data that had been provided by the Association of British Healthcare Industries (ABHI) on behalf of the manufacturers from the CRPS clinical trial. The Committee agreed that these utility data appropriately reflected a group of people with CRPS who may be treated with SCS and that these data should be considered as part of the appraisal. The Committee therefore examined an analysis completed using the Assessment Group's model that included the utility data from the CRPS trial. It acknowledged that the results of analysis using these data produced an ICER of less than 17,000 pounds sterling per OALY gained when using a device price of 9,000 pounds sterling. The Committee was also mindful of consultee comments that device longevity may be greater than the 4year period used in the economic modelling. The Committee recognised that increasing device longevity would further reduce the ICER. The Committee was therefore persuaded that the use of SCS for the treatment of CRPS would be a cost-effective use of NHS resources.

The Committee noted that the manufacturers had not provided an economic evaluation of the use of SCS for ischaemic pain, and that the Assessment Group had only been able to complete exploratory threshold analyses for RA because of limited availability of evidence. Examining the analyses for RA, the Committee considered that their relevance was limited as they were based on a population of people for whom treatment with coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) was suitable. However, these revascularisation techniques are often unsuitable for people with RA. The Committee concluded that although the clinical evidence suggested that there may be groups of people with RA and CLI who could benefit from SCS, there was insufficient evidence on survival and benefits in health-related quality of life (HRQoL), as well as on cost effectiveness. It therefore concluded that the use of SCS for the treatment of chronic pain of ischaemic origin could currently not be recommended.

See Sections 4.2 and 4.3 in of the original guideline document for a detailed discussion of the cost-effectiveness analysis.

## **METHOD OF GUIDELINE VALIDATION**

External Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

# RECOMMENDATIONS

## **MAJOR RECOMMENDATIONS**

Spinal cord stimulation is recommended as a treatment option for adults with chronic pain of neuropathic origin who:

- Continue to experience chronic pain (measuring at least 50 mm on a 0-100 mm visual analogue scale) for at least 6 months despite appropriate conventional medical management
- Have had a successful trial of stimulation as part of the assessment specified below

Spinal cord stimulation is not recommended as a treatment option for adults with chronic pain of ischaemic origin except in the context of research as part of a clinical trial. Such research should be designed to generate robust evidence about the benefits of spinal cord stimulation (including pain relief, functional outcomes and quality of life) compared with standard care.

Spinal cord stimulation should be provided only after an assessment by a multidisciplinary team experienced in chronic pain assessment and management of people with spinal cord stimulation devices, including experience in the provision of ongoing monitoring and support of the person assessed.

When assessing the severity of pain and the trial of stimulation, the multidisciplinary team should be aware of the need to ensure equality of access to treatment with spinal cord stimulation. Tests to assess pain and response to spinal cord stimulation should take into account a person's disabilities (such as physical or sensory disabilities), or linguistic or other communication difficulties, and may need to be adapted.

If different spinal cord stimulation systems are considered to be equally suitable for a person, the least costly should be used. Assessment of cost should take into account acquisition costs, the anticipated longevity of the system, the stimulation requirements of the person with chronic pain and the support package offered.

People who are currently using spinal cord stimulation for the treatment of chronic pain of ischaemic origin should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

# CLINICAL ALGORITHM(S)

None provided

# **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

# TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### **POTENTIAL BENEFITS**

Appropriate use of spinal cord stimulation (SCS) for chronic neuropathic or ischemic pain

#### **POTENTIAL HARMS**

It is acknowledged that spinal cord stimulation (SCS) is not suitable for everyone with chronic pain, and that it should be used only as part of a multidisciplinary team approach with other therapies and a strategy for rehabilitation. Reintervention may be necessary to replace the SCS device because of complications (component failures, lead position or implant-related adverse events such as infection) or when the power source is depleted. Ongoing care of patients is also required, which includes 24-hour availability for the investigation and management of potentially serious problems.

Details of contraindications and potential complications can be found in the implant manual for each SCS component.

# **CONTRAINDICATIONS**

#### **CONTRAINDICATIONS**

Details of contraindications and potential complications can be found in the implant manual for each spinal cord stimulation (SCS) component.

# **QUALIFYING STATEMENTS**

## **QUALIFYING STATEMENTS**

- This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Health professionals are expected to take it fully into account when exercising their clinical judgment. This guidance does not, however, override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting

equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

## **IMPLEMENTATION OF THE GUIDELINE**

## **DESCRIPTION OF IMPLEMENTATION STRATEGY**

- The Healthcare Commission assesses the performance of National Health Service (NHS) organizations in meeting core and developmental standards set by the Department of Health in "Standards for better health" issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by the National Institute for Health and Clinical Excellence (NICE) technology appraisals normally within 3 months from the date that NICE publishes the guidance. Core standard C5 states that healthcare organisations should ensure they conform to NICE technology appraisals.
- "Healthcare Standards for Wales" was issued by the Welsh Assembly
  Government in May 2005 and provides a framework both for self-assessment
  by healthcare organisations and for external review and investigation by
  Healthcare Inspectorate Wales. Standard 12a requires healthcare
  organisations to ensure that patients and service users are provided with
  effective treatment and care that conforms to NICE technology appraisal
  guidance. The Assembly Minister for Health and Social Services issued a
  Direction in October 2003 which requires Local Health Boards and NHS Trusts
  to make funding available to enable the implementation of NICE technology
  appraisal guidance, normally within 3 months.
- NICE has developed tools to help organisations implement this guidance (listed below). These are available on the NICE website (www.nice.org.uk//TA159) [see also the "Availability of Companion Documents" field]).
  - Costing report and costing template to estimate the saving and costs associated with implementation
  - Implementation advice on how to put the guidance into practice and national initiatives which support this locally
  - Audit support for monitoring local practice

# **IMPLEMENTATION TOOLS**

Audit Criteria/Indicators
Patient Resources
Ouick Reference Guides/Physician Guides

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

## **IOM CARE NEED**

Living with Illness

#### **IOM DOMAIN**

Effectiveness Patient-centeredness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

# **BIBLIOGRAPHIC SOURCE(S)**

National Institute for Health and Clinical Excellence (NICE). Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Oct. 33 p. (Technology appraisal guidance; no. 159).

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

#### **DATE RELEASED**

2008 Oct

# **GUIDELINE DEVELOPER(S)**

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

# **SOURCE(S) OF FUNDING**

National Institute for Health and Clinical Excellence (NICE)

## **GUIDELINE COMMITTEE**

Appraisal Committee

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Professor A E Ades, Professor of Public Health Science, Department of Community Based Medicine, University of Bristol; Dr Amanda Adler, Consultant Physician, Cambridge University Hospitals Trust; Ms Anne Allison, Nurse Clinical Adviser, Healthcare Commission; Dr Tom Aslan, General Practitioner, The Hampstead Group Practice, London; Professor David Barnett (Chair), Professor of Clinical Pharmacology, Leicester Royal Infirmary; Dr Matt Bradley, Head of HTA and Business Environment, sanofi-aventis Ltd; Mrs Elizabeth Brain, Lay Member; Mr David Chandler, Lay Member; Simon Dixon, Reader in Health Economics, University of Sheffield; Mrs Fiona Duncan, Clinical Nurse Specialist, Anaesthetic Department, Blackpool Victoria Hospital, Blackpool; Mr John Goulston, Chief Executive, Barking, Havering and Redbridge Hospitals NHS Trust; Mrs Eleanor Grey, Lay Member; Professor Philip Home (Vice Chair), Professor of Diabetes Medicine, Newcastle University; Dr Vincent Kirkbride,

Consultant Neonatologist, Regional Neonatal Intensive Care Unit, Sheffield; Dr Alec Miners, Lecturer in Health Economics, London School of Hygiene and Tropical Medicine; Dr Ann Richardson, Lay Member; Mrs Angela Schofield, Chairman, Bournemouth and Poole Teaching PCT; Mr Mike Spencer, General Manager, Facilities and Clinical Support Services, Cardiff and Vale NHS Trust; Dr Simon Thomas, Consultant Physician and Reader in Therapeutics, Newcastle Hospitals NHS Foundation Trust and Newcastle University; Mr David Thomson, Lay Member

# FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

# **GUIDELINE STATUS**

This is the current release of the guideline.

#### **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

#### **AVAILABILITY OF COMPANION DOCUMENTS**

The following are available:

- Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Oct. 2 p. (Technology appraisal 159). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin.
   Costing template and report. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Oct. Various p. (Technology appraisal 159).
   Available in Portable Document Format (PDF) from the NICE Web site.
- Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. Audit support. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008. 6 p. (Technology appraisal 159). Available in Portable Document Format (PDF) from the <u>NICE Web site</u>.
- Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin.
   Assessment report. 2008 Jun. 248 p. Available in Portable Document Format (PDF) from the <u>NICE Web site</u>.
- Guide to the technology appraisal process. 2004 May. 31 p. Available in Portable Document Format (PDF) from the <u>NICE Web site</u>.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1699. 11 Strand, London, WC2N 5HR.

## **PATIENT RESOURCES**

The following is available:

Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin.
 Understanding NICE guidance - Information for people who use NHS services.
 London (UK): National Institute for Health and Clinical Excellence (NICE);
 2008 Oct. 7 p. (Technology appraisal 159).

Electronic copies: Available in Portable Document Format (PDF) from the <u>National</u> Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N1700. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

#### **NGC STATUS**

This NGC summary was completed by ECRI Institute on January 8, 2009.

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